

**REMARKS**

**Status of the Claims**

Claims 1-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81, 87-89 and 96-99 are pending. Claims 8-10, 13-15, and 96-99 have been withdrawn from consideration. Claim 11 has been amended to eliminate the dependency on non-elected claim 10 and to more particularly point out the invention. Support for this amendment is found in the specification on page 25, line 29-page 26 line 16; page 15, lines 14-16; page 26, lines 10-16; page 30, lines 15-19; and claims 10 and 11 as originally filed. Claims 27, 37, 47, 57, 67, 77 and 87 have been amended to merely correct a typographical error. The amendments are supported in the specification on page 24, lines 24-27. Claims 31, 41, 51, 61, 71 and 81 have been amended to merely correct a typographical error. The amendments are supported in the specification on page 7, lines 3-8; page 8, lines 14-17; page 9, lines 25-28; page 11, lines 5-9; page 12, lines 16-19; and page 13, lines 21-24. Claim 1 has been amended to more particularly point out the invention. The amendment is supported on page 4, lines 19-20; page 5, lines 24-27; page 7, lines 4-6; page 8, lines 14-17; page 9, lines 25-28; page 11, lines 5-8; page 16, line 1-page 17, line 2. No new matter has been added by this amendment.

**Objections to the Claims**

Claims 11 and 12 are objected to as being dependent on non-elected claims. Claim 11 has been amended herein and is now an independent claim. Claim 12 depends on claim 11. Applicants have thus addressed the Office's objection. Claims

27, 37, 47, 57, 67, 77 and 87 are objected to because the word "of" is missing between "a culture" and "a host cell." Claims 27, 37, 47, 57, 67, 77 and 87 have been amended to recite the word "of" as suggested by the Office. Applicants have thus addressed the Office's objection.

### **Indefiniteness**

Claims 31, 41, 51, 61, 71 and 81 stand rejected under 35 U.S.C. §112 second paragraph for alleged indefiniteness. These claims are dependent claims. The Office alleges the claims recite a SEQ ID NO which is outside the scope of the independent claim from which each of these claims depends. These claims contained an inadvertent typographical error which has been corrected by this amendment, thus obviating the rejection.

### **Written Description**

Claims 1-7, 11-12 and 16-18 stand rejected under 35 U.S.C. §112 first paragraph for alleged lack of written description. The Office alleges that the claimed invention contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. Without conceding the correctness of the rejection, and for the sole purpose of expediting prosecution, applicants have amended claim 1 herein. Claims 2-7 and 16-18 all depend on claim 1, directly or indirectly. The amendment thus obviates the rejection with respect to each of these claims.

The Office alleges that claims 11-12 fail to provide functional limitations with respect to the mocarhagin protein. Applicants point out that the claims are a product by process claim. In other words, they claim a mocarhagin protein obtained by a specific method. Thus, the claimed protein may be obtained by following the process steps recited in the claims. Applicants are not describing the properties of the protein of claims 11-12 functionally, but are instead describing the specific process steps that must be taken in order to isolate it.

A description as filed is presumed adequate and the Office is reminded that it bears the burden in establishing that the written description is inadequate. M.P.E.P. §2163.04. Applicants note that the Office has provided no legal basis to support the rejection of claims 11-12 for alleged lack of written description. While it appears the Office is attempting to apply the written description standard enunciated in *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997), Applicants submit this decision is inapposite to the rejection of claims 11-12. This case explores the application of the written description requirement to composition claims. *Id.* The courts have not established that the requirements for claiming a DNA sequence by its activity are the same as product-by-process claims. The Office cannot simply ignore this issue. Moreover, claims 11-12 do provide physical process steps for one to use in the isolation of the claimed peptides. Accordingly, Applicants respectfully request withdrawal of the rejection.

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## **Enablement**

Claims 20, 21, 30, 31, 40, 41, 50, 51, 60, 61, 70, 71, 80 and 81 stand rejected under 35 U.S.C. §112 first paragraph for alleged lack of enablement. The Office acknowledges that Applicants have deposited several clones encoding mocarhagin proteins, but questions whether the deposit was made pursuant to the Budapest treaty. Applicants submit the Declaration of M. Andrea Ryan with this amendment which states that the deposit meets the requirements of the Budapest treaty. The rejection is thus obviated.

Claims 1-7, 11-12 and 16-18 stand rejected under 35 U.S.C. §112 first paragraph for alleged lack of enablement. The Office admits the specification enables certain specific sequences, or fragments thereof, disclosed in the specification, but alleges the specification does not provide enablement for any mocarhagin protein.

### **A. The Standard For Enablement**

"The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.* 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). "A patent need not teach and preferably omits what is well known in the art." *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); MPEP § 2164.01.

### **B. The Composition Claims**

Without conceding the correctness of the rejection, and for the sole purpose of expediting prosecution, Applicants have amended claim 1 herein. Claims 2-7 and 16-18

either depend on claim 1 or depend on a dependent claim which depends on claim 1.

The amendment thus obviates the rejection with respect to each of these claims.

### C. Product By Process Claims

Applicants submit claims 11-12 are indeed enabled. As stated above claims 11-12 are product by process claims. Claim 11 recites specific steps a skilled artisan could follow to obtain the claimed protein. Moreover, the specification discloses at page 18, lines 1-7 "a protein is defined as having 'mocarhagin proteolytic activity' when (1) it digests PSGL-1, such as in a PSGL-1 digestion assay described in Example 3 below, and/or (2) inhibits the binding of P-selectin to neutrophils or HL60 cells, such as in the binding inhibition assay described in Example 2 below, and/or (3) cleaves a peptide derived from PSGL-1 (pyroEATEYEYLDYDFLPE SEQ ID NO:3) such as in the peptide cleavage assay described in Example 4."

A skilled artisan is taught not only how to isolate the claimed protein from cobra venom, but is also provided with detailed instructions to determine if the isolated protein is a mocahagin protein (see the specification at page 18, lines 7-12; page 26, line 25- page 28, line 31). The assays disclosed require merely routine techniques. The skilled artisan would thus be able to practice the invention without any undue experimentation. *In re Wands* 858 F.2d 731, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988). Accordingly, Applicants respectfully request withdrawal of the enablement rejection of claims 11-12.

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## Anticipation

Claims 1-2, 4-7, 11, 12, 16-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81 and 87-89 stand rejected under 35 U.S.C. §102(b) or 102(e) as allegedly anticipated by U.S. Patent No. 5, 659,018 (Berndt) or DeLuca et al. 1995, *J. Biol. Chem.* 270(45):26734. The Office admits the purification method taught by the cited references is not the same as the one disclosed in the specification (*i.e.* the disclosed method contains a final mono S column purification step). The Office further admits that it cannot determine the purity of the protein disclosed in the cited references and that claim 1 recites "mocarhagin protein at least 95% free of other cobra proteins." Nonetheless, the Office alleges that each reference anticipates the claimed invention.

### A. The Anticipation Standard

The standard required for finding anticipation under 35 U.S.C. § 102(b) is stated in MPEP § 2131 (emphasis added). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). 'The identical invention must be shown in as complete detail as is contained in the . . . claim'. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989)." Neither Deluca or Berndt meet this standard.

### B. The Composition Claims

Claims 1-2, 4-7 and 16-17 recite compositions "comprising a mocarhagin protein at least 95% free of other cobra proteins." Neither Deluca nor Berndt disclose the

claimed composition. The Office admits that it cannot determine if the proteins disclosed in Deluca or Berndt are indeed "95% free of other cobra proteins." Applicants submit that the cited references do not teach each and every element of the invention and thus cannot anticipate it. The composition disclosed in Berndt and DeLuca must be "95% free of other cobra proteins." The references do not disclose this and thus are not anticipatory.

The Office attempts to argue that the claims are inherently anticipated by Deluca or Berndt because the references teach a purification scheme that is similar to the one disclosed in the instant specification. The Office seems to suggest that the possibility that the claimed protein is present in the composition disclosed in the references is enough to establish inherent anticipation. This is not the case. It is impossible for the Office to conclude that the claimed composition is inherently anticipated by the two cited references when the Office admits it cannot tell if the protein disclosed in the references is 95% free of other cobra proteins. The Office provides no extrinsic evidence to support the allegation of inherent anticipation. See M.P.E.P. §2131.01. If the protein disclosed in the references is not 95% free of other proteins then the references do not anticipate the claimed invention either inherently or explicitly.

Moreover, claim 1 has been amended herein and now recites specific sequences. Applicants note that the claimed sequences are indeed different from the sequence disclosed in the Berndt reference (see column 2, lines 27-31).

Accordingly, claims 1-2 and 4-7 are not anticipated by either Berndt or DeLuca and Applicants respectfully request withdrawal of the rejection.

### C. Product by Process Claims

As discussed above claims 11-12 recite a product by process. The process includes a final mono S column purification step. Neither cited reference recites this step and the Office admits this. Accordingly, the references do not teach each and every element of the claimed invention and thus neither reference anticipates the claimed invention. Applicants respectfully request withdrawal of the anticipation rejection with respect to claims 11-12.

### D. Claims Reciting Specific Sequences

Claims 18-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81 and 87-89 all recite specific sequences of specific mocarhagin proteins. None of these specific proteins are disclosed in either reference cited by the Office. As discussed above, Berndt actually teaches an N terminal sequence that is different from any sequence disclosed in the instant specification. Accordingly these claims are not anticipated by either reference and Applicants respectfully request withdrawal of the rejection with respect to each of these claims.

### Obviousness

Claims 1-2, 4-7, 11, 12, 16-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81 and 87-89 stand rejected under 35 U.S.C. §103 as being obvious over the same two references cited for anticipation (Berndt and DeLuca). The Office has not established the claimed invention is *prima facie* obvious.



### **A. The Obviousness Standard**

MPEP § 2143 provides the standard required to establish a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations." The Office bears the burden of establishing a prima facie case of obviousness. The Office has not met its burden.

### **B. The Composition Claims**

Claims 1-2, 4-7 and 16-17 recite compositions "comprising a mocarhagin protein at least 95% free of other cobra proteins." Neither Deluca nor Berndt disclose the claimed composition because neither reference teaches "a mocarhagin protein at least 95% free of other cobra proteins" and combining the two references does not cure this defect. Moreover claim 1, as amended herein, recites specific sequences not disclosed in either reference. Because the references combined do not teach each and every element of the claimed invention the Office has failed to establish the claimed invention is prima facie obvious. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection of claims 1-2, 4-7 and 16-17.

### **C. Product by Process Claims**

As discussed above claims 11-12 recite a product by process. The process includes a final mono S column purification step. Neither cited reference recites this

step and the Office admits this. Accordingly, the combined references do not teach each and every element of the claimed invention and thus cannot render the claimed invention obvious.

Applicants submit many protein purification protocols were known in the art at the time of the invention. There is nothing of record to suggest a mono S column would be successful in isolating mocrhagin proteins. Using a mono S column would have been merely obvious to try. Obvious to try is not the proper basis for a 103 rejection.

*O'Farrell*, 853 F.2d 894, 7 U.S.P.Q.2d 1673, (Fed. Cir. 1988). Accordingly, there is nothing of record to indicate purifying mocrhagin proteins using a mono S column would offer a reasonable chance of success. Claims 11-12 are therefore not prima facie obvious.

#### **D. Claims Reciting Specific Sequences**

Claims 18-21, 27-31, 37-41, 47-51, 57-61, 67-71, 77-81 and 87-89 all recite specific sequences of specific mocrhagin proteins. None of these specific proteins are disclosed in either reference cited by the Office. Combining the cited references does not cure this defect. Accordingly these claims are not rendered obvious by the combined references and Applicants respectfully request withdrawal of the obviousness rejection with respect to each of these claims.

#### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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